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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,797	03/15/2000	Athanasius A Anagnostou	5218-39B	9917
20792 7	590 08/05/2002			
MYERS BIG	EL SIBLEY & SAJOVE	EXAMINER		
PO BOX 37428			UNGAR, SUSAN NMN	
RALEIGH, NO	27627		01107111,50	57114 1414114
			ART UNIT	PAPER NUMBER
			1642	$\alpha$
			DATE MAILED: 08/05/2002	7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/525,797 Applicant(s)

Anagnostou et al

Examiner

Ungar

Art Unit 1642



The MAILING DATE of this communication appears	on the cover sheet with the correspondence address				
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the					
mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.					
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply a</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the</li> </ul>					
<ul> <li>Any reply received by the Office later than three months after the mailing date of t earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	his communication, even if timely filed, may reduce any				
Status					
1) X Responsive to communication(s) filed on Jun 26, 2					
2a) ☐ This action is FINAL. 2b) ☐ This act	ion is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
Disposition of Claims					
4) 💢 Claim(s) <u>12-15 and 17-25</u>	is/are pending in the application.				
4a) Of the above, claim(s)	is/are withdrawn from consideration.				
5) Claim(s)	is/are allowed.				
6) X Claim(s) 12-15 and 17-25					
7) Claim(s)	is/are objected to.				
8) Claims	are subject to restriction and/or election requirement.				
Application Papers					
9) The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. L Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
*See the attached detailed Office action for a list of the	·				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
a) ☐ The translation of the foreign language provisional application has been received.  7 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s).					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:				

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1. The Amendment filed June 26, 2002 (Paper No. 8) in response to the Office Action of March 20, 2002 (Paper No. 7) is acknowledged and has been entered. Previously pending claims 12-15 and 17-25 are currently being examined.

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. The following rejections are maintained:

#### Claim Rejections - 35 USC § 112

5. Claims 12-15 and 17-25 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 7, Section 5, pages 3-10.

Applicant argues that one of skill in the art would know how to practice the invention. The argument has been considered but has not been found persuasive for the reasons previously set forth. Further, it is noted that Applicant has not addressed the critical issues drawn to the biphasic effects of EPO and dosage, the contradictory evidence of the Anagnostou Declaration. Applicant's arguments have not been found persuasive and the rejection is maintained.

### Claim Rejections - 35 USC § 102

6. Claims 12-15 and 21, 23-25 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 7, Section 9, pages 11-12.

Applicant argues that the treatment disclosed by Platanias et al is not the same as that claimed. The argument has been considered but has not been found persuasive because the method of the prior art comprises the same method steps as claimed in the instant invention, to the same population, thus the claimed method is anticipated because the method will inherently treat the solid vascularized tumor.

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Applicant's arguments have not been found persuasive and the rejection is maintained.

#### Claim Rejections - 35 USC § 103

7. Claims 12-15 and 17-25 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 7, Section 9, pages 11-12.

Applicant argues that the references either alone or in combination fail to suggest all of the claim recitations of the present invention. The argument has been considered but has not been found persuasive for the reasons set forth above and further because the art clearly teaches that administration of intravenous cisplatin is a conventional protocol in the treatment of solid tumors. Applicant's arguments have not been found persuasive and the rejection is maintained.

- 8. All other objections and rejections recited in Paper No. 7 are withdrawn.
- 9. No claims allowed.
- 10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

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# STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

Primary Patent Examiner

August 1, 2002